CMS Manual System Pub. 100-04 Medicare Claims Processing	Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)				
Transmittal 382	Date: NOVEMBER 26, 2004				
-	CHANCE DECLIEST 3/67				

CHANGE REQUEST 3467

SUBJECT: Independent Laboratory Billing for the Technical Component (TC) of Physician Pathology Services to Hospital Patients

I. SUMMARY OF CHANGES: This Change Request (CR) implements Section 732 of the Medicare Modernization Act that extends the provision of Section 542 of the Benefits Improvement and Protection Act (BIPA) for services furnished in 2005 and 2006. Section 542 of BIPA allows the carrier to continue to pay independent laboratories under the physician fee schedule for the technical component of physician pathology services furnished to patients of a covered hospital. This CR also adds previous material included in the Medicare Carriers Manual but omitted from the Internet Only Manual, Pub. 100-04, Claims Processing.

We will issue a subsequent CR in the near future to address the systems implications of this policy.

NEW/REVISED MATERIAL - EFFECTIVE DATE: January 1, 2005 *IMPLEMENTATION DATE: January 3, 2005

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	12/60/Payment for Pathology Services

*III. FUNDING:

These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

X	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

^{*}Unless otherwise specified, the effective date is the date of service.

Attachment - Business Requirements

Pub. 100-04 Transmittal: 382 Date: November 26, 2004 Change Request: 3467

SUBJECT: Independent Laboratory Billing for the Technical Component (TC) of Physician Pathology Services to Hospital Patients

I. GENERAL INFORMATION

A. Background:In the final physician fee schedule published in the **Federal Register** on November 2, 1999, CMS stated that it would implement a policy to pay only hospitals for the technical component (TC) of physician pathology services furnished to hospital inpatients. Prior to this proposal, any independent laboratory could bill the carrier under the physician fee schedule for the TC of physician pathology services to a hospital inpatient.

The regulation provided that, for services furnished on or after January 1, 2001, the carrier would no longer pay claims to the independent laboratory under the physician fee schedule for the TC of physician pathology services for hospital inpatients. Similar treatment was provided under the outpatient prospective payment system for the TC of physician pathology services to hospital outpatients. This change was to take effect for services furnished on or after January 1, 2001. The delay was intended to allow independent laboratories and hospitals sufficient time to negotiate arrangements.

However, Section 542 of the Benefits Improvement Act of 2000 (BIPA) provided that the Medicare carrier could continue to pay for the TC of physician pathology services when an independent laboratory furnishes this service to an inpatient or outpatient of a covered hospital. Section 542 applied only to services furnished during calendar years 2001 and 2002.

For this provision, covered hospital means a hospital that had an arrangement with an independent laboratory that was in effect as of July 22, 1999, under which a laboratory furnished the TC of physician pathology services to fee-for-service Medicare beneficiaries who were hospital inpatients or outpatients, and submitted claims for payment for the TC service to a carrier. The TC could have been submitted separately or combined with the professional component and reported as a combined service.

CMS administratively extended this provision for services furnished in 2003 (through Transmittal B-03-001, Change Request 2530, published on January 17, 2003) and 2004 (through Transmittal 34, One Time Notification, Change Request 3028, published on December 24, 2003).

Section 732 of the Medicare Modernization Act (MMA) extends Section 542 of the BIPA for services furnished during 2005 and 2006.

B. Policy: Section 542 of BIPA was implemented through Transmittal AB-01-47 (Change Request 1499) issued on March 22, 2001. This transmittal was renumbered and reissued in December 2002 and remained in effect for 2003. This transmittal was incorporated in the Internet Only Manual (i.e., Publication 100-04 Claims Processing Manual, Chapter 12, §60, Payment for Pathology Services) in October 2003, as part of the overhaul of CMS' manuals.

The October 2003 revision did not correctly incorporate the material in Transmittal AB-01-47. Also, this revision omitted the policy previously included under the "General Payment Rule" that allows a hospital laboratory to bill for the TC service to non-hospital patients. We have added this policy in the manual. We have also updated the manual to account for Section 732 of the MMA that extends Section 542 of BIPA for services furnished in calendar years 2005 and 2006.

We will issue a subsequent CR in the near future that will address the systems implications of this policy.

C. Provider Education: A Medlearn Matters provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly

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BUSINESS REQUIREMENTS II.

"Shall" denotes a mandatory requirement "Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility (place an "X" in the columns that apply)								
							Shared System Maintainers			Other
		FI	RHHI	Carrier	DMERC	FISS	MCS	VMS	CWF	
3467.1	Until further notice, the carrier shall allow those independent laboratories that had an arrangement established with a covered hospital, on or prior to July 22, 1999, to bill for the Technical Component of physician pathology services to continue to bill for these services under the Medicare Physician Fee Schedule.			X						
3467.2	Until further notice, the carrier shall allow independent laboratories that have acquired another independent laboratory that had an arrangement established with a covered hospital, on or prior to July 22, 1999, to bill for the Technical Component of physician pathology services to continue to bill for these services when furnished to the covered hospital's inpatients and/or outpatients.			X						

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions:

X-Ref Requirement #	Instructions	
3467.1	The carrier shall require independent laboratories that had an arrangement established with a covered hospital, on or prior to July 22, 1999, to bill for the Technical Component of physician pathology services to provide a copy of this agreement, or other documentation substantiating that an arrangement was in effect between the hospital and the independent laboratory as of this date, for each covered hospital that the independent laboratory services.	
3467.2	Until further notice, the carrier shall maintain, for postpayment reviews, a hard copy of documentation submitted by independent laboratories to confirm that an arrangement was in effect between the hospital and the independent laboratory as of July 22, 1999 to bill for the Technical Component of physician pathology services.	

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements				

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: January 1, 2005	Medicare Contractors shall
Implementation Date: January 3, 2005	implement these instructions within their current operating budgets.
Pre-Implementation Contact(s): James Menas, 410-786-4507	buugets.
Post-Implementation Contact(s): Appropriate Regional Office	

^{*}Unless otherwise specified, the effective date is the date of service.

60 - Payment for Pathology Services

(Rev. 382, Issued: 11-26-04, Effective: 01-01-05, Implementation: 01-03-05)

B3-15020, AB-01-47 (CR1499)

A - General Payment Rule

Payment may be made under the fee schedule for the professional component of physician laboratory or physician pathology services furnished to hospital inpatients or outpatients by hospital physicians or by independent laboratories, if they qualify as the reassignee for the physician service. Payment may be made under the fee schedule, as noted below, for the technical component (TC) of pathology services furnished by an independent laboratory to hospital inpatients or outpatients. Payment may be made under the fee schedule for the technical component of physician pathology services furnished by an independent laboratory, or a hospital if it is acting as an independent laboratory, to non-hospital patients. The Medicare physician fee schedule identifies those physician laboratory or physician pathology services that have a technical component service.

CMS published a final regulation in 1999 that would no longer allow independent laboratories to bill under the physician fee schedule for the TC of physician pathology services. The implementation of this regulation was delayed by Section 542 of the Benefits and Improvement and Protection Act of 2000 (BIPA). Section 542 allows the Medicare carrier to continue to pay for the TC of physician pathology services when an independent laboratory furnishes this service to an inpatient or outpatient of a covered hospital. This provision is applicable to TC services furnished in 2001, 2002, 2003, 2004, 2005 or 2006.

For this provision, a covered hospital is a hospital that had an arrangement with an independent laboratory that was in effect as of July 22, 1999, under which a laboratory furnished the TC of physician pathology services to fee-for-service Medicare beneficiaries who were hospital inpatients or outpatients, and submitted claims for payment for the TC to a carrier. The TC could have been submitted separately or combined with the professional component and reported as a combined service.

The term, fee-for-service Medicare beneficiary, means an individual who:

- 1. Is entitled to benefits under Part A or enrolled under Part B of title XVIII or both; and
- 2. Is not enrolled in any of the following: A Medicare + Choice plan under Part C of such title; a plan offered by an eligible organization under §1876 of the Social Security Act; a program of all-inclusive care for the elderly under §1894; or a social health maintenance organization demonstration project established under Section 4108 of the Omnibus Budget Reconciliation Act of 1987.

In implementing Section 542, the carriers should consider as independent laboratories those entities that it has previously recognized as independent laboratories.

An independent laboratory that has acquired another independent laboratory that had an arrangement of July 22, 1999, with a covered hospital, can bill the TC of physician pathology services for that hospital's inpatients and outpatients under the physician fee schedule. An independent laboratory that furnishes the TC of physician pathology services to inpatients or outpatients of a hospital that is not a covered hospital may not bill the carrier for the TC of physician pathology services during the time §542 is in effect.

If the arrangement between the independent laboratory and the covered hospital limited the provision of TC physician pathology services to certain situations or at particular times, then the independent laboratory can bill the carrier only for these limited services.

The carrier shall require independent laboratories that had an arrangement, on or prior to July 22, 1999 with a covered hospital, to bill for the technical component of physician pathology services to provide a copy of this agreement, or other documentation substantiating that an arrangement was in effect between the hospital and the independent laboratory as of this date. The independent laboratory must submit this documentation for each covered hospital that the independent laboratory services.

See Chapter 16 for additional instruction on laboratory services including clinical diagnostic laboratory services.

Physician laboratory and pathology services are limited to:

- Surgical pathology services;
- Specific cytopathology, hematology and blood banking services that have been identified to require performance by a physician and are listed below;
- Clinical consultation services that meet the requirements in subsection D below; and
- Clinical laboratory interpretation services that meet the requirements and which are specifically listed in subsection E below.

B - Surgical Pathology Services

Surgical pathology services include the gross and microscopic examination of organ tissue performed by a physician, except for autopsies, which are not covered by Medicare. Surgical pathology services paid under the physician fee schedule are reported under the following CPT codes:

88300, 88302, 88304, 88305, 88307, 88309, 88311, 88312, 88313, 88314, 88318, 88319, 88321, 88323, 88325, 88329, 88331, 88332, 88342, 88346, 88347, 88348, 88349, 88355, 88356, 88358, 88361, 88362, 88365, 88360.

Depending upon circumstances and the billing entity, the carriers may pay professional component, technical component or both.

C - Specific Hematology, Cytopathology and Blood Banking Services

Cytopathology services include the examination of cells from fluids, washings, brushings or smears, but generally excluding hematology. Examining cervical and vaginal smears are the most common service in cytopathology. Cervical and vaginal smears do not require interpretation by a physician unless the results are or appear to be abnormal. In such cases, a physician personally conducts a separate microscopic evaluation to determine the nature of an abnormality. This microscopic evaluation ordinarily does require performance by a physician. When medically necessary and when furnished by a physician, it is paid under the fee schedule.

These codes include 88104, 88106, 88107, 88108, 88112, 88125, 88141, 88160, 88161, 88162, 88172, 88173, 88180, 88182.

For services furnished prior to January 1, 1999, carriers pay separately under the physician fee schedule for the interpretation of an abnormal pap smear furnished to a hospital inpatient by a physician. They must pay under the clinical laboratory fee schedule for pap smears furnished in all other situations. This policy also applies to screening pap smears requiring a physician interpretation. For services furnished on or after January 1, 1999, carriers allow separate payment for a physician's interpretation of a pap smear to any patient (i.e., hospital or non-hospital) as long as: (1) the laboratory's screening personnel suspect an abnormality; and (2) the physician reviews and interprets the pap smear.

This policy also applies to screening pap smears requiring a physician interpretation and described in the National Coverage Determination Manual and Chapter 18. These services are reported under codes P3000 or P3001.

Physician hematology services include microscopic evaluation of bone marrow aspirations and biopsies. It also includes those limited number of peripheral blood smears which need to be referred to a physician to evaluate the nature of an apparent abnormality identified by the technologist. These codes include 85060, 38220, 85097, and 38221.

Carriers pay the professional component for the interpretation of an abnormal blood smear (code 85060) furnished to a hospital inpatient by a hospital physician or an independent laboratory.

For the other listed hematology codes, payment may be made for the professional component if the service is furnished to a patient by a hospital physician or independent laboratory. In addition, payment may be made for these services furnished to patients by an independent laboratory.

Codes 38220 and 85097 represent professional-only component services and have no technical component values.

Blood banking services of hematologists and pathologists are paid under the physician fee schedule when analyses are performed on donor and/or patient blood to determine compatible

donor units for transfusion where cross matching is difficult or where contamination with transmissible disease of donor is suspected.

The blood banking codes are 86077, 86078, and 86079 and represent professional component only services. These codes do not have a technical component.

D - Clinical Consultation Services

Clinical consultations are paid under the physician fee schedule only if they:

- 1. Are requested by the patient's attending physician;
- 2. Relate to a test result that lies outside the clinically significant normal or expected range in view of the condition of the patient;
- 3. Result in a written narrative report included in the patient's medical record; and
- 4. Require the exercise of medical judgment by the consultant physician.

Clinical consultations are professional component services only. There is no technical component. The clinical consultation codes are 80500 and 80502.

Routine conversations held between a laboratory director and an attending physician about test orders or results do not qualify as consultations unless all four requirements are met. Laboratory personnel, including the director, may from time to time contact attending physicians to report test results or to suggest additional testing or be contacted by attending physicians on similar matters. These contacts do not constitute clinical consultations. However, if in the course of such a contact, the attending physician requests a consultation from the pathologist, and if that consultation meets the other criteria and is properly documented, it is paid under the fee schedule.

EXAMPLE

A pathologist telephones a surgeon about a patient's suitability for surgery based on the results of clinical laboratory test results. During the course of their conversation, the surgeon ask the pathologist whether, based on test results, patient history and medical records, the patient is a candidate for surgery. The surgeon's request requires the pathologist to render a medical judgment and provide a consultation. The pathologist follows up his/her oral advice with a written report and the surgeon notes in the patient's medical record that he/she requested a consultation. This consultation is paid under the fee schedule.

In any case, if the information could ordinarily be furnished by a nonphysician laboratory specialist, the service of the physician is not a consultation payable under the fee schedule. See the Program Integrity Manual for guidelines for related data analysis to identify inappropriate patterns of billing for consultations.

E - Clinical Laboratory Interpretation Services

Only clinical laboratory interpretation services listed below and which meet the criteria in subsections D.1, D.3, and D.4 for clinical consultations and, as a result, are billable under the fee schedule. These services are reported under the clinical laboratory code with modifier 26. These services can be paid under the physician fee schedule if they are furnished to a patient by a hospital pathologist or an independent laboratory. Note that a hospital's standing order policy can be used as a substitute for the individual request by the patient's attending physician. Carriers are not allowed to revise CMS's list to accommodate local medical practice. The CMS periodically reviews this list and adds or deletes clinical laboratory codes as warranted.

Clinical Laboratory Interpretation Services

Code	Definition	
83020	Hemoglobin; electrophoresis	
83912	Nucleic acid probe, with electrophoresis, with examination and report	
84165	Protein, total, serum; electrophoretic fractionation and quantitation	
84181	Protein; Western Blot with interpretation and report, blood or other body fluid	
84182	Protein; Western Blot, with interpretation and report, blood or other body fluid,	
	immunological probe for band identification; each	
85390	Fibrinolysin; screening	
85576	Platelet; aggregation (in vitro), any agent	
86255	Fluorescent antibody; screen	
86256	Fluorescent antibody; titer	
86320	Immunoelectrophoresis; serum, each specimen	
86325	Immunoelectrophoresis; other fluids (e.g.urine) with concentration, each	
	specimen	
86327	Immunoelectrophoresis; crossed (2 dimensional assay)	
86334	Immunofixation electrophoresis	
87164	Dark field examination, any source (e.g. penile, vaginal, oral, skin); includes	
	specimen collection	
87207	Smear, primary source, with interpretation; special stain for inclusion bodies or	
	intracellular parasites (e.g. malaria, kala azar, herpes)	
88371	Protein analysis of tissue by Western Blot, with interpretation and report.	
88372	Protein analysis of tissue by Western Blot, immunological probe for band	
	identification, each	
89060	Crystal identification by light microscopy with or without polarizing lens	
	analysis, any body fluid (except urine)	